BRIEF FOR APPELLEE DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE

United States Court of Appeals For the Federal Circuit

Appeal No. 01-1307
Serial No. 08/252,384

IN RE C. STEVEN MCDANIEL, FRANK M. RAUSHEL AND JAMES R. WILD

Appeal from the United States Patent and Trademark Office,
Board of Patent Appeals and Interferences

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STATEMENT OF RELATED CASES

The Director is not aware of any other appeal from the Board of Patent Appeals and Interferences in connection with application Serial No. 08/252,384 that has previously been before this or any other court. There is no other known related case pending in this or any other court. The Director is also unaware of any other cases pending in this or any other court that will directly affect or be directly affected by this Court's decision in the pending appeal.

STATEMENT OF JURISDICTION

The Director agrees with Appellants' statement of jurisdiction.

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I. STATEMENT OF THE ISSUES

1. Whether the Board's determination that the '384 application's claimed invention is anticipated by any one of four references, *i.e.*, (i) McDaniel (BY), (ii) Harper, (iii) McDaniel (AZ), or (iv) Wild, is supported by substantial evidence.

2. Whether the Board committed reversible error in finding that the Harper and McDaniel (BY) references were proper prior art against the '384 application.

II. STATEMENT OF THE CASE

This appeal arose out of the examination of patent application Serial No. 08/252,384 ('384 application) by C. Steven McDaniel, Frank M. Raushel and James R. Wild. (A1).[1] Claims 53-64 are at issue in this appeal. (A5).

A. The Claimed Subject Matter

The '384 application is directed to a method of detoxifying an organophosphorous compound by exposing the compound to a recombinant bacterial organophosphorous acid anhydrase. (A23). Simply put, the invention is for a method of exposing a toxic compound to a specific enzyme, an anhydrase, that detoxifies the compound, rendering it harmless.

Organophosphorous neurotoxins may be found in agricultural and domestic pesticides, as well as nerve gases in chemical warfare arsenals. (A20). Because of increased usage of such compounds in modern society, numerous environmental problems have arisen. (A20). The main concern is the lack of a safe and efficient means of disposal of these compounds. (A20). The '384 application seeks to address this concern by providing a safe method for detoxifying

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[1] Citations to Appellants' Brief will be referred to as "Br. at __," and citations to the Joint Appendix as "A__."

organophosphorous compounds using a recombinant bacterial organophosphorous acid anhydrase. (A23).

Specifically, an organophosphorous detoxifying gene (opd) is inserted into an expression vector and transformed into a bacteria to produce a recombinant bacterial organophosphorous acid anhydrase enzyme derivative. (A23). The opd anhydrase enzyme can be used to detoxify organophosphorous compounds. (A23).

Claim 53 is illustrative of the subject matter on appeal and reads:

> **53.** A method for detoxifying an organophosphorus compound comprising exposing said compound to recombinant bacterial organophosphorus acid anhydrase.

(A83). The Board found that Appellants grouped the remaining rejected claims so that claims 54-64 stand or fall with claim 53. 37 C.F.R. § 1.192(c)(7). (A5).

B. The Prior Art

Representative claim 53 is rejected pursuant to § 102 based on any one of the following four prior art references (i) McDaniel (BY), (ii) Harper, (iii) McDaniel (AZ), or (iv) Wild.[2]

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[2] **(i)** C. Steven McDaniel *et al.*, Cloning and Sequencing of a Plasmid-Borne Gene (*opd*) Encoding a Phosphotriesterase, J. of Bacteriology, May 1988 at 2306-11 (McDaniel (BY)); **(ii)** Linda L. Harper *et al.*, Dissimilar Plasmids Isolated from *Pseudomonas diminuta* MG and a *Flavobacterium* sp. (ATCC 27551) Contain Identical *opd* Genes, Applied and Environmental Microbiology, Oct. 1988 at 2586-89 (Harper); **(iii)** C. Steven McDaniel, *Ph.D. Dissertation*, Plasmid-Mediated Degradation of Organophosphate Pesticides, Texas A&M University

1. McDaniel (BY)

McDaniel (BY) discloses cloning and sequencing techniques of the opd gene. (A121, 1178). Specifically, McDaniel (BY) isolated DNA containing the opd gene from a naturally occurring bacteria known to have the ability to detoxify organophosphorus compounds and created a recombinant plasmid containing the opd gene. (A1178). Next, McDaniel (BY) transformed the recombinant plasmid into another bacteria and found that that bacteria now possessed the ability to detoxify organophosphorus compounds. (A1181-82). McDaniel (BY) also provides a nucleotide sequence for the opd gene as well as a partial amino acid sequence for the anhydrase protein. (A1181).

2. Harper

Harper discusses degradation of organophosphorous compounds using bacteria transformed with the opd gene. (A1184). Specifically, Harper teaches that different plasmids isolated from two different strains of bacteria (P. diminuta and Flavobacterium (sp) (ATCC 27551)) contain identical opd genes. (A1184-85).

(1985) (McDaniel (AZ)); and **(iv)** J.R. Wild *et al.*, Cloning, Sequencing and Characterization of *OPD* Genes and Their Broad-Spectrum Organophosphate Hydrolases from Soil Bacteria, *Proceedings of the 1986 U.S. Army Chemical Research, Development and Engineering Center Scientific Conference on Chemical Defense Research* at 629-34 (1986) (Wild).

3. McDaniel (AZ)

McDaniel (AZ) discloses that a gene isolated from soil bacteria known to have the ability to detoxify organophosphorus compounds can be inserted into a plasmid and transformed into bacteria to produce an enzyme having the same detoxification ability. (A1122-23). This gene is known to be the opd gene. (A1122-23). McDaniel (AZ) shows that when organophosphorus compounds are exposed to the recombinant enzyme produced by transformed bacteria, the compounds are hydrolyzed. (A1107-14).

4. Wild

Wild discloses that the opd gene has been isolated from two strains of bacteria and that the protein enzymes of both are found to be able to detoxify organophosphorus compounds. (A1172-73). Wild shows that bacteria transformed with the recombinant opd gene acquire the degradative quality and detoxify organophosphorous compounds. (A1173). Further, Wild determined the nucleotide sequence of the isolated opd gene. (A1175-76).

C. The Board Decision

The Board affirmed the examiner's finding that claims 53-64 are anticipated under 35 U.S.C. § 102(b) by McDaniel (AZ) or by Wild, and that claims 53-64 are anticipated under 35 U.S.C. § 102(a) by McDaniel (BY) or Harper. (A16). As

noted by the Board, the examiner made specific factual findings as to what the four prior art references teach in his Examiner's Answer. (A621-772). The Board adopted these factual findings made by the examiner. (A4, 13, 16). Appellants did not challenge the factual findings made by the examiner with respect to the prior art references. Instead, Appellants made two arguments, both of which the Board rejected. First, Appellants argued that McDaniel (BY) and Harper are not proper prior art references under § 102(a) because the authors of those articles are also the inventors of the '384 application with two exceptions. (A447-50). Appellants argued that these exceptions are nullified by the Declaration of Invention that was filed with the '384 application. (A447-50). Second, Appellants argued that McDaniel (AZ) and Wild do not bar the claimed invention under § 102(b) because the disclosures in those references are incomplete and do not cover the claimed invention. (A450-53).

The Board first acknowledged Appellants' statement that "[c]laims 53-64 are all properly of a single group." (A5, 428). Thus, the Board only considered whether claim 53 was anticipated by the prior art because claim 53 was representative of claims 53-64. (A5). Consequently, the decision as to the

patentability of claim 53 was dispositive of the question of patentability of the remaining claims. (A5).[3]

Next, the Board construed claim 53 as being limited to a method for detoxifying an organophosphorus compound by exposing that compound to a recombinant bacterial organophosphorous acid anhydrase. (A5). The Board found that this enzyme is identical to the enzyme that occurs in nature in certain bacteria from which the encoding DNA has been isolated. (A5-6). The Board pointed out that none of the disputed claims are directed to the DNA that encodes the claimed recombinant anhydrase *per se* but instead claim the use of an enzyme having the ability to detoxify organophosphorous compounds. (A6). The Board went on to find that although some claims provide that the recombinant anhydrase is produced by a transformed organism that includes the specific DNA coding sequence, these are process of preparation limitations and do not serve to distinguish the claimed enzyme from another enzyme from a different source also having the ability to detoxify organophosphorous compounds. (A6).

With respect to the § 102(a) and § 102(b) rejections, the Board affirmed the examiner's anticipation rejections of claims 53-64 over McDaniel (BY), Harper,

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[3] *See, e.g., In re King*, 801 F.2d 1324, 1325, 231 USPQ 136, 137 (Fed. Cir. 1986); *In re Dance*, 160 F.3d 1339, 1340 n.2, 48 USPQ2d 1635, 1636 n.2 (Fed. Cir. 1998).

Wild, and McDaniel (AZ). (A16). It found that each of these references describes the use of a recombinant bacterial organophosphorus acid anhydrase for the detoxification of an organophosphorus compound. (A13). Consequently, because each of the references provide a description of the claimed process that meets all of the limitations of claim 53, each serves to establish a *prima facie* case of anticipation of the claimed subject matter. (A13).

The Board found that both McDaniel (BY) and Harper constitute prior art under 35 U.S.C. § 102(a) because they were both published prior to the earliest filing date of the claimed invention. (A13). At the time of the Board's decision, Appellants had not filed a declaration under 37 C.F.R. § 1.132 to clarify inventorship/authorship of the publications. (A13). The Board rejected Appellants' contentions that the initial Declaration of Invention filed with the patent application in combination with statements of record indicating that certain authors of the prior art publications were not also co-inventors, were sufficient to remove McDaniel (BY) and Harper as prior art. (A14). Specifically, the Board reasoned that the initial Declaration of Invention was insufficient because it does not explicitly identify any prior publication nor does it state that only the '384 application inventors are the inventors of the subject matter disclosed in McDaniel (BY) and Harper. (A14).

The Board next rejected Appellants' argument that Wild is inapplicable as prior art because it does not teach the DNA sequence of the opd gene or the initiation codon necessary for expression of the gene. (A15). The Board found that claim 53 is not directed to the opd gene or the use thereof, therefore, Wild is proper prior art. (A15). Moreover, because Appellants offered no evidence that the "anhydrase encoded by the opd gene described in the specification differs from the anhydrase explicitly described in McDaniel (BY), Harper, or Wild," the Board affirmed the examiner's anticipation rejections. (A15). Similarly, the Board found that Appellants provided no evidence to reasonably prove that the enzyme in the claim 53 differs from the enzyme used in McDaniel (AZ) and thus claim 53 is anticipated by this reference as well. (A15).

III. SUMMARY OF THE ARGUMENT

The Board found that Appellants' representative claim 53 is directed to a method of exposing a toxic compound (organophosphorous compound) to a specific enzyme (recombinant bacterial organophosphorous acid anhydrase) that detoxifies the compound, rendering it harmless. The Board also found that claim 53 does not have a DNA sequence feature. Therefore, claim 53 is generic in the

sense that any recombinant bacterial organophosphorous acid anhydrase is included regardless of its sequence.

As the examiner found and the Board agreed, McDaniel (AZ)'s disclosure is a statutory bar to the appealed claims under 35 U.S.C. § 102(b) because McDaniel (AZ) was available in 1985, more than one year before Appellants' filing date. McDaniel (AZ) explicitly discloses all of the limitations found in claim 53 of the '384 application and therefore anticipated that claim. Because representative claim 53 is anticipated by McDaniel (AZ), claims 54-64 are similarly unpatentable over that reference.

As the examiner found and the Board agreed, Wild's disclosure anticipates the appealed claims because Wild explicitly discloses all of the limitations found in claim 53 of the '384 application. Therefore, because Wild teaches every limitation of claim 53 and was available more than one year before Appellants' filing, Wild bars the patentability of that claim under § 102(b). Because representative claim 53 is anticipated by Wild, claims 54-64 are similarly unpatentable over that reference.

As the examiner found and the Board agreed, McDaniel (BY)'s disclosure anticipates the appealed claims because McDaniel (BY) explicitly discloses all of the limitations found in claim 53 of the '384 application. Because all of the

limitations of claim 53 are found in McDaniel (BY), it is clear that that reference anticipates claim 53 and those claims grouped with it under 35 U.S.C. § 102(a) and the Board should be affirmed.

As the examiner found and the Board agreed, Harper anticipates claim 53 of the '384 application because it discloses that organophosphorus compounds may be detoxified using a recombinant bacterial plasmid containing the opd gene that produces organophosphorous acid anhydrase, thus disclosing both limitations of claim 53. Because representative claim 53 is anticipated by Harper, claims 54-64 are similarly unpatentable over that reference.

Appellants' argument that Wild and McDaniel (AZ) teach away from the claimed invention because neither reference provides the nucleotide sequence for the opd gene is without merit. The question of whether a reference "teaches away" from the invention is inapplicable to an anticipation analysis. Even if the teaching away argument were relevant, claim 53, the representative claim, does not require that a nucleotide sequence be known. All that is required to anticipate the claim 53 is that the prior art reference disclosure teaches exposing an organophosphorous compound to a recombinant bacterial organophosphorus acid anhydrase. Further, as the examiner found, only routine sequencing would have been needed to determine the sequence. Here, both Wild and McDaniel (AZ) teach exposing an

organophosphorous compound to a recombinant bacterial organophosphorus acid anhydrase and therefore anticipate claims 53-64 of the '384 application.

McDaniel (BY) and Harper are § 102(a) references because the authors of these references differ from the inventors listed on the '384 application. Appellants' argument that McDaniel (BY) and Harper are not a proper prior art references because a co-authored, pre-filing publication of an inventor may be removed as prior art is misplaced. There is no continuity of authorship and inventorship on these prior art references and the '384 application respectively. Specifically, Harper and Miller are listed as authors on McDaniel (BY) and Harper, but not as inventors on the '384 application. Appellants never followed any proper procedure for removing the McDaniel (BY) and Harper as prior art references. Appellants did not file disclaiming declarations from Harper and Miller under 37 C.F.R. § 1.132. Nor did Appellants add Harper and Miller as inventors of the '384 application. Therefore, McDaniel (BY) and Harper are proper § 102(a) prior art.

The Board properly grouped claims 54-64 with claim 53 because Appellants stated that the claims should be treated as a single group and did not separately argue the claims on appeal. Appellants did nothing more than mention the content of the dependent claims in their appeal brief before the Board. Appellants did not

argue the merits of each dependent claim, nor did they distinguish those claims from the prior art, therefore, claims 54-64 stand or fall with claim 53.

Appellants contention that the Amgen patent is relevant to the prosecution of the '384 application is incorrect. The Amgen patent is not part of the record that was before the Board. Consequently, the Board never addressed this issue and Appellants are raising a new issue on appeal, something this Court has strictly prohibited. Therefore, this Court should not consider Appellants' arguments regarding the Amgen patent. Should the Court should find that Appellants' Amgen patent arguments are properly before it, the USPTO addresses those arguments directly. It is well-settled that the prosecution of one patent application does not dictate or affect the prosecution of another patent application. The Amgen patent is markedly different from the '384 application because Amgen's claims are directed to a DNA molecule encoding a particular amino acid sequence, a recombinant plasmid, a transformed microorganism, and a method for producing only a protein having that particular amino acid sequence. Appellants' representative claim is directed to a method of detoxifying organophosphorus compounds using recombinant bacterial organophosphorus acid anhydrase. Thus, the inventions claimed are not the same.

IV. ARGUMENT

A. Standard of Review

Appellants have the burden of showing that the Board committed reversible error. *In re Caveney*, 761 F.2d 671, 674, 226 USPQ 1, 3 (Fed. Cir. 1985). Claim construction is a question of law reviewed *de novo* on appeal. *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1454, 46 USPQ2d 1169, 1173 (Fed. Cir. 1998) (*en banc*). Because claims during prosecution must be given their "broadest reasonable interpretation" by the United States Patent and Trademark Office (USPTO), this Court reviews the USPTO's interpretation of disputed claim language to determine whether it is "reasonable" in light of all the evidence before the Board. *In re Morris*, 127 F.3d 1048, 1054, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997). Whether a reference is prior art is a question of law that this Court reviews *de novo*. *Panduit Corp. v. Dennison Mfg, Co.*, 810 F.2d 1561, 1568 n.9, 1 USPQ2d 1593, 1597 n.9 (Fed. Cir. 1987).

Anticipation, as well as what a reference teaches, is a question of fact. *Rapoport v. Dement*, 254 F.3d 1053, 1058, 59 USPQ2d 1215, 1218 (Fed. Cir. 2001); *In re Hyatt*, 211 F.3d 1367, 1371-1372, 54 USPQ2d 1664, 1667 (Fed. Cir. 2000). This Court has held that the Board's factual determinations must be upheld unless they are unsupported by substantial evidence. *In re Gartside*, 203 F.3d

1305, 1316, 53 USPQ2d 1769, 1776 (Fed. Cir. 2000). This Court has defined substantial evidence:

> Substantial evidence is more than a mere scintilla. It means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion. . . . Mere uncorroborated hearsay or rumor does not constitute substantial evidence.

Id. at 1312, 53 USPQ2d at 1773 (quoting *Consolidated Edison Co. v. NLRB*, 305 U.S. 197, 229 (1938)). The Supreme Court has stated that "the possibility of drawing two inconsistent conclusions from the evidence does not prevent an administrative agency's finding from being supported by substantial evidence." *Consolo v. Federal Maritime Comm'n*, 383 U.S. 607, 620 (1966).

B. Claims 53-64 Are Anticipated by the Prior Art of Record

Anticipation analysis is a two-step process. First, the claims must be properly construed. *Elmer v. ICC Fabricating, Inc.*, 67 F.3d 1571, 1574, 36 USPQ2d 1417, 1419 (Fed. Cir. 1995); *see also Rockwell Int'l Corp. v. United States*, 147 F.3d 1358, 1362, 47 USPQ2d 1027, 1029 (Fed. Cir. 1998) ("The first step in any invalidity or infringement analysis is claim construction."). During *ex parte* prosecution, Appellants' claims must be given their broadest reasonable interpretation consistent with the specification. *In re Graves*, 69 F.3d 1147, 1152, 36 USPQ2d 1697, 1701 (Fed. Cir. 1995). Therefore, this Court must determine

"whether the PTO's interpretation of the disputed claim language is 'reasonable.'" *Morris*, 127 F.3d at 1055, 44 USPQ2d at 1028-29.

The second step in the anticipation analysis is to determine whether all elements of the claim, as properly construed, are disclosed in the prior art reference either explicitly or inherently. *Rapoport*, 254 F.3d at 1058, 59 USPQ2d at 1218; *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997).

1. The Board Properly Construed Claim 53 as Being Limited to a Method for Detoxifying an Organophosphorus Compound

The Board construed claim 53 as being limited to a method for detoxifying an organophosphorus compound by exposing that compound to a recombinant bacterial organophosphorous acid anhydrase. (A5). The Board found that the anhydrase enzyme used is identical to the anhydrase enzyme that occurs in nature in certain bacteria from which the encoding DNA has been isolated. (A5-6). The Board rejected Appellants' attempt to read a DNA sequence into claim 53. (A6). The Board pointed out that none of the disputed claims are directed to the DNA that encodes the claimed recombinant anhydrase *per se* but instead claim the use of an anhydrase enzyme having the ability to detoxify organophosphorous compounds. (A6). Specifically, the Board found that claim 53 does not have a "sequence" feature. (A16). Thus, claim 53 is generic in the sense that any

recombinant bacterial organophosphorous acid anhydrase is included regardless of its sequence.[4]

2. The Examiner Made a Detailed Fact-Finding as to What Each Prior Art Reference Teaches and How It Reads on the Representative Claim And the Board Adopted These Findings

Appellants did not challenge the Examiner's factual findings at the Board, nor do they challenge those findings here before this Court. These findings are summarized below for the Court's convenience.

a. McDaniel (AZ) Bars Patentability of the Claimed Invention Under 35 U.S.C. § 102(b)

As the examiner found (A642) and the Board agreed, McDaniel (AZ)'s disclosure is a statutory bar to the appealed claims under 35 U.S.C. § 102(b) because McDaniel (AZ) explicitly discloses all of the limitations found in claim 53 of the '384 application. (A16).

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[4] The Board did find that although some claims provide that the recombinant anhydrase is produced by a transformed organism that includes the specific DNA coding sequence, these are process of preparation limitations and do not serve to distinguish the claimed enzyme from another enzyme from a different source also having the ability to detoxify organophosphorous compounds. (A6).

Claim 53:	**Prior Art McDaniel (AZ):**
A method for detoxifying an organophosphorus compound comprising	"A plasmid of approximately 51 Kbp has been isolated from a strain of Pseudomonas diminuta shown to possess a phosphotriesterase capable of the hydrolytic cleavage of a wide range of organophosphate pesticides. When fragments of the plasmid were subcloned into pBR322, a recombinant molecule containing a 1270 bp PstI insert was found to be capable of expressing the degradative phenotype in E. coli." (A642, 1122). The detoxification assay is also shown. (A642, 1057-58).
exposing said compound to recombinant bacterial organophosphorous acid anhydrase.	Showing the opd gene that has been transformed into a recombinant plasmid and host cell expresses a phosphotriesterase that hydrolyzes a wide range of organophosphate pesticides. (A642, 1122-24).

McDaniel (AZ) was available in 1985, more than one year before Appellants' filing date. Therefore, the Board correctly found that McDaniel (AZ) bars the patentability of claim 53 under § 102(b). (A16). Because representative claim 53 is anticipated by McDaniel (AZ), claims 54-64 are similarly unpatentable over that reference.

b. Wild Bars Patentability of the Claimed Invention Under 35 U.S.C. § 102(b)

As the examiner found (A641-42) and the Board agreed, Wild's disclosure anticipates the appealed claims because Wild explicitly discloses all of the limitations found in claim 53 of the '384 application. (A16).

Claim 53:	**Prior Art Wild:**
A method for detoxifying an organophosphorus compound comprising	"Two organophosphate degrading genes (opd) have been identified and subcloned from nonhomologous plasmids isolated from divergent soil bacteria." (A641-42, 1172).
exposing said compound to recombinant bacterial organophosphorous acid anhydrase.	An opd gene from a bacteria was isolated and transferred into recombinant plasmids and transformed into a host bacteria (*E. coli*). The resulting recombinant protein enzyme was shown to be a organophosphorous acid anhydrase. (A641-42, 1173, 1176). The opd gene was found to be 1300 base pairs. (A1175).

Wild discloses that opd genes are found in naturally occurring soil bacteria. (A1172). Wild states that the gene produces a broad-spectrum organophosphate hydrolase, also known as organophosphorous acid anhydrase. (A1172). Wild isolated the opd gene from this naturally occurring bacteria and transferred it into a new bacterial plasmid forming a recombinant DNA product. (A1173). Wild next transformed this recombinant plasmid into a new bacterial host that expressed the

protein enzyme product. (A1173). Wild tested the enzyme product's ability to degrade (*i.e.*, detoxify) organophosphate compounds. (A1173). Wild found that the opd gene recombinant enzyme product did indeed have the ability to detoxify organophosphate compounds. (A1173-74). Then, Wild discloses that he cloned and sequenced the opd genes. (A1175). Wild found that the opd gene from two different sources of soil bacteria each had a DNA sequence of 1300 base pairs and were virtually identical. (A1175-76). Lastly, Wild characterized the recombinant enzyme protein and found that it acts in the same manner as the naturally occurring protein in that it has the ability to detoxify organophosphate compounds. (A1176).

It is evident from this disclosure of Wild that every limitation of claim 53 can be found in that reference. Claim 53 has two limitations, 1) a method for detoxifying organophosphate compounds and 2) achieving detoxification by exposing the organophosphate compound to recombinant bacterial organophosphorous acid anhydrase. (A475). The chief objective of the Wild reference is to detoxify organophosphate compounds (limitation 1). (A1173). Wild teaches that this detoxification is achieved by exposing the compounds to recombinant bacterial organophosphorous acid anhydrase (limitation 2). (A1173, 1176-1177). Moreover, Wild teaches how to make the organophosphorous acid anhydrase using a recombinant bacterial plasmid containing the opd gene.

(A1176). Therefore, because Wild teaches every limitation of claim 53 and was available more than one year before Appellants' filing, Wild bars the patentability of that claim under § 102(b). Because representative claim 53 is anticipated by Wild, claims 54-64 are similarly unpatentable over that reference.

c. McDaniel (BY) Anticipates the Claimed Invention Under 35 U.S.C. § 102(a)

As the examiner found (A640-41) and the Board agreed, McDaniel (BY)'s disclosure anticipates the appealed claims because McDaniel (BY) explicitly discloses all of the limitations found in claim 53 of the '384 application. (A16).

Claim 53:	**Prior Art McDaniel (BY):**
A method for detoxifying an organophosphorus compound comprising	"*Pseudomonas putatida* and *Flavobacterium* ssp. have been shown to possess the ability to degrade an extremely broad spectrum of organophosphorus phosphotriesters as well as thiol esters." (A640-41, 1178).
exposing said compound to recombinant bacterial organophosphorous acid anhydrase.	"In the present study, the *opd* gene from *Pseudomonas diminuta* was sequenced and its membrane-associated gene product was expressed . . . ." (A640-41, 1178). The opd gene was transferred into a recombinant plasmid and then into host cell and the resulting protein enzyme was shown to be a organophosphorous acid anhydrase. (A640-41, 1179). The nucleotide sequence for the opd gene is also provided. (A640-41, 1181).

McDaniel (BY) is directed to the cloning and sequencing of the opd gene that encodes organophosphorous acid anhydrase. (A1178). McDaniel (BY) found that two naturally occurring bacteria, *Pseudomonas putatida* and *Flavobacterium* ssp., were known to have the ability to detoxify organophosphorus compounds. (A1178). McDaniel (BY) isolated the opd gene from a naturally occurring bacteria, transferred it into a recombinant plasmid, and expressed the resulting protein enzyme. (A1178). Additionally, McDaniel (BY) studied the enzyme product from the naturally-occurring bacteria. (A1178).

McDaniel (BY) discloses both claim limitations. First, McDaniel (BY) states that it is well known that certain strains of naturally-occurring bacterial have the ability to detoxify organophosphorus compounds. (A1178). This meets the first limitation of claim 53. Next, McDaniel (BY) isolates the opd gene that is known to be responsible for the detoxification. (A1178-79). McDaniel (BY) discloses that it is known that the opd gene expresses a product known as a phosphotriesterase or an organophosphorous acid anhydrase. (A1178). Therefore, McDaniel (BY) next creates a recombinant plasmid using the isolated opd gene to create a vehicle for producing recombinant bacterial organophosphorous acid anhydrase. (A1179). Finally, McDaniel (BY) tests the resulting protein product and concludes that it is a functional recombinant bacterial organophosphorous acid anhydrase. (A1180-81). This meets the second limitation of claim 53. Additionally, McDaniel (BY) provides the nucleotide sequence of the opd gene. (A1181). Because all of the limitations of claim 53 are found in McDaniel (BY), it is clear that that reference anticipates claim 53 and those claims grouped with it under 35 U.S.C. § 102(a) and therefore the Board should be affirmed.

d. Harper Anticipates the Claimed Invention Under 35 U.S.C. § 102(a)

As the examiner found (A641) and the Board agreed, Harper's disclosure anticipates the appealed claims because Harper explicitly discloses all of the limitations found in claim 53 of the '384 application. (A16).

Claim 53:	**Prior Art Harper:**
A method for detoxifying an organophosphorus compound comprising	"*Pseudomonas diminuta* and *Flavobacterium* sp. (ATCC27551) have the ability to degrade a broad spectrum of organophosphorus triesters by virtue of a constitutively expressed organophosphorous acid anhydrase ." (A641, 1184).
exposing said compound to recombinant bacterial organophosphorous acid anhydrase.	Harper extracted the opd gene from two separate naturally-occurring bacteria found to hydrolyze organophosphorous compounds. (A641, 1184). Both genes were sequenced and found to be identical. (A641, 1184). The product of the genes was an organophosphorous acid anhydrase. (A641, 1186). Harper teaches production of a recombinant bacterial organophosphorous acid anhydrase and demonstrates detoxification of organophosphorus compounds by exposing the compound to the recombinant enzyme. (A641, 1184).

Harper concerns a sequence study that determined that the opd gene of two separate strains of soil bacteria have identical nucleotide sequences. (A1184). Harper discloses that the soil bacteria containing the opd gene have the ability to detoxify organophosphorus compounds. (A1184). Harper reports that it is the enzyme that is produced by expression of the opd gene in a recombinant bacterial system, called organophosphorous acid anhydrase, that is responsible for the detoxification of the organophosphorus compounds. (A1184). Also, Harper reports the nucleotide sequence of the opd gene. (A1185). It is evident that Harper anticipates claim 53 of the '384 application because it discloses that organophosphorus compounds may be detoxified using a recombinant bacterial plasmid containing the opd gene that produces organophosphorous acid anhydrase, thus disclosing both limitations of claim 53. (A475). Because representative claim 53 is anticipated by Harper, claims 54-64 are similarly unpatentable over that reference.

C. The Board Correctly Rejected Appellants' Two Technical Arguments As to Why the Prior Art References Are Not Effective

1. McDaniel (AZ) and Wild Are Proper § 102(b) References Because They Disclose the Claimed Invention

Appellants argue that Wild and McDaniel (AZ) teach away from the claimed invention because neither reference provides the nucleotide sequence for the opd

gene.[5] (Br. at 15). However, the question of whether a reference "teaches away" from the invention is inapplicable to an anticipation analysis. As this Court stated in *Celeritas Technologies Ltd. v. Rockwell International Corp.*, 150 F.3d 1354, 1361, 47 USPQ2d 1516, 1522 (Fed. Cir. 1998), "[t]he fact that [the claimed element disclosed in the reference] is shown to be less than optimal does not vitiate the fact that it is disclosed." *See also Atlas Powder Co. v. IRECO, Inc.*, 190 F.3d 1342, 1348-49, 51 USPQ2d 1943, 1948 (Fed. Cir. 1999) (claimed composition anticipated by prior art reference that inherently met claim limitation "sufficient aeration" even though reference taught away from air entrapment or purposeful aeration).

Even if the teaching away argument were relevant, only routine sequencing would have been needed to determine the sequence, as the examiner found. (A666). However, claim 53, the representative claim, does not require that a nucleotide sequence be known. (A16). All that is required to anticipate the claim is that the prior art reference disclosure teaches exposing an organophosphorous compound to a recombinant bacterial organophosphorus acid anhydrase. *See, e.g., In re Paulsen*, 30 F.3d 1475, 1480, 31 USPQ2d 1671, 1674 (Fed. Cir. 1994) (*post*

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[5] Appellants have not argued that the prior art enzymes are not "recombinant bacterial organophosphorous acid anhydrase[s]."

hoc attempt to redefine the claimed invention by incorporating extraneous language from the specification is impermissible); *Amhill Enterprises Ltd. v. Wawa, Inc.*, 81 F.3d 1554, 1559, 38 USPQ2d 1471, 1474 (Fed. Cir. 1996) (scope of claims is not necessarily or automatically limited to a preferred embodiment). Here, both Wild and McDaniel (AZ) teach exposing an organophosphorous compound to a recombinant bacterial organophosphorus acid anhydrase and therefore anticipate claims 53-64 of the '384 application. (A641-42, 1122-24, 1172-73).

Appellants' argument that Wild's teaching would not lead to a functional enzyme contradicts the reference's reported success. (Br. at 14-15). Appellants assert that Wild's "preferred" method deletes a flanking region of the opd gene and would not work. (Br. at 14-15). However, Wild plainly states "the entire degradative plasmid was subcloned into the PstI site of the bla gene of pBR322 and parathion-degrading transformants of E. coli HB101-4442 were identified." (A1175). Thus, Wild does indeed anticipate the claimed invention. Appellants' new argument about Wild's additional teaching to enhance expression by deleting part of the 5'-flanking sequence is irrelevant, even if there were evidence for its veracity, because it is merely an alternative teaching.

Both McDaniel (AZ) and Wild taught how to obtain a plasmid containing

the opd gene and how to recombine it to express the functional enzyme. (A1000-01, 1175). Thus, it remains that both McDaniel (AZ) and Wild teach detoxifying an organophosphate compound by exposing the compound to a recombinant bacterial organophosphorus acid anhydrase. This teaching discloses all of the limitations of the appealed claims.

2. McDaniel (BY) and Harper Are Proper § 102(a) References Because Appellants' Submissions Did Not Establish Continuity of Authorship and Inventorship

McDaniel (BY) and Harper are § 102(a) references because the authors of these references differ from the inventors listed on the '384 application. Therefore, there is not continuity of authorship and inventorship. McDaniel (BY) includes Linda L. Harper in addition to two of the '384 application inventors. (A1178). Harper includes Linda L. Harper and Charles E. Miller in addition to two of the '384 application inventors. (A1184). Appellants argue that McDaniel (BY) and Harper are not a proper prior art references because a co-authored, pre-filing publication of an inventor may be removed as prior art. (Br. at 8-10). However, Appellants did not use any effective procedure to remove McDaniel (BY) or Harper as a prior art reference. There are several methods one can employ to remove a publication as prior art. One method is to file § 1.132 declarations by the non-inventor co-authors, here Linda L. Harper and Charles E. Miller, stating that

they are not inventors of the claimed subject matter. *See* Manual of Patent Examining Procedure (MPEP) § 715.01(c) (Feb. 2000). It is also possible to overcome the rejection by adding the co-authors as inventors if the requirements of 35 U.S.C. § 116 are met. *In re Searles*, 422 F.2d 431, 435-36, 164 USPQ 623, 627-28 (CCPA 1970). Appellants chose not to use either of these methods.[6] Instead, Appellants are attempting to rely on the initial Declaration of Invention as well as statements made during prosecution as a means for removing McDaniel (BY) and Harper as prior art. However, these means are insufficient under the MPEP, 37 C.F.R. § 1.132, and relevant case law to effect such removal.

Appellants specifically rely upon *In re Katz*, 687 F.2d 450, 215 USPQ 14 (CCPA 1982), as support for their argument that McDaniel (BY) and Harper have effectively been removed as prior art. (Br. at 9, 11-12). However, the declaration in *Katz* is substantially different. There, Katz's declaration stated that he is a co-author of a publication in the proceedings of the National Academy of Science, and the "sole inventor of the subject matter described and claimed in his application" and publication. *Id.* at 452 & 455, 215 USPQ at 15-16 & 18. The declaration further explained that the co-authors of the publication in question were students

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[6] Although Appellants discuss a "disclaiming" affidavit or declaration in their brief, they did not actually do so. (Br. at 9) Instead, they now offer to submit such declarations or affidavits if the Board is affirmed. (Br. at 9).

who worked under Katz's direction and supervision. *Id.* at 455, 215 USPQ at 16. Reversing the Board's inference that the students' names identified them as co-inventors, this Court's predecessor reasoned that Katz made a reasonable showing that supported his position as sole inventor. *Id.* Simply put, the Court found that Katz's relationship with his students does not automatically infer joint inventorship in the face of sworn statements. *Id.* at 456, 215 USPQ at 16. Hence, Katz made sufficient showing that the cited publication disclosed his invention. *Id.*

The case at bar is markedly different from *Katz*. As found by the Board, Appellants' Declaration of Invention does not explicitly identify the publications they are attempting to remove as prior art. (A14-15). Further, the Board found that the Declaration did not state that only the '384 application inventors are the inventors of the subject matter disclosed in McDaniel (BY). (A14). The Board also found that the Declaration was deficient because it does not explain that the other co-authors of McDaniel (BY) and Harper, namely Harper and Miller, worked in conjunction with or under the direction or supervision of the '384 application inventors. (A14-15). Appellants' failure to incorporate this information into the Declaration of Invention renders the Declaration ambiguous and incomplete. Thus, the Declaration is insufficient to remove McDaniel (BY) and Harper as prior art. *Katz*, 687 F.2d at 455-56, 215 USPQ at 18 ("It was incumbent, therefore, on

appellant to provide a satisfactory showing which would lead to a reasonable conclusion that he is the sole inventor.").

D. The Board Properly Grouped Claims 54-64 with Claim 53 Because Appellants Stated That the Claims Should Be Treated as a Single Group and Did Not Separately Argue the Claims on Appeal

The Board found that "[at] page 11 of the Brief on Appeal, appellants state that '[c]laims 53-64 are all properly of a single group.' We interpret this to mean that, as to questions of patentability raised by this appeal, the claims stand and fall together." (A5). The Board found that "the patentability of claim 53 is considered dispositive of the question of patentability of the remaining claims." (A5). For this, the Board relied upon 37 C.F.R. § 1.192(c)(7), which states:

> For each ground of rejection which appellant contests and which applies to a group of two or more claims, the Board shall select a single claim from the group and shall decide the appeal as to the ground of rejection on the basis of that claim alone unless a statement is included that the claims of the group do not stand or fall together and, in the argument under paragraph (c)(8) of this section, appellant explains why the claims of the group are believed to be separately patentable. Merely pointing out differences in what the claims cover is not an argument as to why the claims are separately patentable.

Here, Appellants stated that the Board should consider all the claims as a single group. (A428). Further, Appellants did not separately argue the patentability of claims 54-64 over the prior art of record before the Board. In their appeal brief to the Board, Appellants simply argued "claim 53 and those claims depending from

it." (*See, e.g.* A463-64). Therefore, there is no argument as to why the dependent claims are separately patentable over the prior art as is required by Rule 192(c)(7).

This Court has articulated what is necessary to have claims argued separately and therefore not treated as a group on appeal to the Board. In *Dance*, 160 F.3d at 1340 n.2, 48 USPQ2d at 1636 n.2, the Court declined to consider the patentability of the appealed claims separately because it found that although the applicant "mentions the content of the dependent claims, he does not argue their merits separately from those of independent claim 33, or attempt to distinguish them from the prior art." *See also In re Herbert*, 461 F.2d 1390, 1391, 174 USPQ 259, 260 (CCPA 1972) (appellant "failed to point out what relevance the additional limitations have to the patentability of the narrower claims" so claims stand or fall together); *In re Nielson*, 816 F.2d 1567, 1572, 2 USPQ2d 1525, 1528 (Fed. Cir. 1987) (appellant "did not challenge with any reasonable specificity before the Board the rejections of the other dependent claims" so claims stand or fall together).

Similarly here, Appellants did nothing more than mention the content of the dependent claims in their appeal brief before the Board. (A427). Appellants did not argue the merits of each dependent claim, nor did they distinguish those claims from the prior art. (A418-74). Therefore, claims 54-64 stand or fall with claim 53.

37 C.F.R. § 1.192(c)(7); *Dance*, 160 F.3d at 1340 n.2, 48 USPQ2d at 1636 n.2.

E. The Amgen Patent Is Not Relevant to the Patentability of the '384 Application

Appellants contend that U.S. Patent No. 5,484,728 to Serdar *et al.* (Amgen patent) (A960-76) is relevant to the prosecution of the '384 application because the inventions are the same. (Br. at 17). Appellants also argue that it is unfair that the USPTO granted the Amgen patent over McDaniel (BY) and Harper, the two principal references cited against the '384 application. (Br. at 17-18). At the outset, it should be noted that the Amgen patent is not part of the record that was before the Board. Appellants raised its arguments for the first time during oral argument before the Board.[7] (Br. at 5). Consequently, the Board never addressed this issue. Thus, Appellants are raising a new issue on appeal, something this Court has strictly prohibited. *Hyatt*, 211 F.3d at 1373, 54 USPQ2d at 1668. Therefore, this Court should not consider Appellants' arguments regarding the Amgen patent.

While we do not believe that the Court should find that Appellants' Amgen patent arguments are properly before it, the USPTO will address those arguments

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[7] The Amgen patent issued on January 16, 1996, well before the November 14, 2000 oral argument before the Board. (A960). Therefore, Appellants had ample opportunity to properly make the Amgen patent part of the record before the USPTO, but failed to do so.

directly. First, it is well-settled that the prosecution of one patent application does not dictate or affect the prosecution of another patent application. *In re Wertheim*, 541 F.2d 257, 264, 191 USPQ 90, 97 (CCPA 1976) ("[I]t is immaterial in *ex parte* prosecution whether the same or similar claims have been allowed to others."). Therefore, the events that took place during the Amgen patent prosecution have no bearing on the prosecution of Appellants' '384 application.

Second, the Amgen patent is markedly different from the '384 application because Amgen's claims are directed to a DNA molecule encoding a particular amino acid sequence, a recombinant plasmid, a transformed microorganism, and a method for producing only a protein having that particular amino acid sequence. (A976). Appellants' representative claim is directed to a method of detoxifying organophosphorus compounds using recombinant bacterial organophosphorus acid anhydrase. (A475). Thus, the inventions claimed are not the same. Moreover, statutorily, the Amgen patent is presumed to be valid. 35 U.S.C. § 282. Thus, even on the merits, Appellants' arguments regarding the Amgen patent must fail. Therefore, this Court should reject Appellants' attempted collateral attack on the validity of Amgen's patent.

V. CONCLUSION

Substantial evidence supports the Board's finding that claims 53-64 are anticipated under 35 U.S.C. § 102 by any one of four references (i) McDaniel (BY),

(ii) Harper, (iii) McDaniel (AZ), (iv) Wild. Furthermore, the Board did not err in its determination that the patentability of claims 54-64 stand or fall with the patentability of claim 53 because they were not separately argued on appeal. Therefore, the Board's decision should be affirmed.

Respectfully submitted,

August 29, 2001

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RULE 32(A)(7)(C) CERTIFICATE OF COMPLIANCE

I certify pursuant to FRAP 32(a)(7) that the foregoing brief complies with the type-volume limitation. The total number of words, as calculated by the Word Perfect 6.1 program is 8065.

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Kristin L. Yohannan

CERTIFICATE OF SERVICE

I certify that on August 29, 2001, I caused two copies of the foregoing BRIEF FOR APPELLEE DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE to be transmitted via FEDERAL EXPRESS addressed as follows:

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Representative Claim

53. A method for detoxifying an organophosphorus compound comprising exposing said compound to recombinant bacterial organophosphorus acid anhydrase.